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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/030,452	01/10/2002	Masayuki Yabuta	58777.000002	5707

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EXAMINER

ROOKE, AGNES BEATA

ART UNIT	PAPER NUMBER
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1653

DATE MAILED: 05/19/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/030,452	YABUTA ET AL.	
	Examiner	Art Unit	
	Agnes B Rooke	1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 20 April 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 3-6 and 8-12 is/are pending in the application.
 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 3-6 and 8-12 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☐ All b) ☐ Some * c) ☒ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This Office Action is in response to the Request for Continued Examination filed on April 20, 2005.

Claims 3-6 and 8-12 are pending and currently under examination.

Claims 1, 2, and 7 has been cancelled.

This application is 371 of PCT/JP01/03909, filed on 05/10/2001.

The Applicant claims priority to JAPAN 2000-137228, filed on 05/10/2000, but the priority documents are not on file. Thus, the Applicant must submit a copy of the priority documents.

Withdrawal of Objections and Rejections

The objections and rejections not explicitly restated or stated below are withdrawn.

New Rejection

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 3-6 and 8-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yabuta et al. (U.S. 5,670,340).

The present invention is directed to a method of producing atrial natriuretic proteins in culture medium or broth that is supplemented with any one of the amino acids histidine, methionine and glycine.

Yabuta et al. teach a process of expression a target peptide in a large amount and accumulation of the target peptide in host cells in the form of occlusion bodies. See Abstract. In Examples 3 and 4 Yabuta et al. teach production of human calcitonin from fusion protein in E.coli. Examples 5-8 teach production of CNP-22 from fusion protein in E.coli.

Yabuta et al. do not teach production of ANP from fusion protein in E.coli.

In column 4, line 20-26, Yabuta et al. state that the method can be applied for production of a fusion protein of physiologically active peptides, for example natriuretic peptides, such as ANP. In Claim 1, Yabuta et al. claim process for the production of a target peptide, where the target peptide can be ANP.

It would have been obvious to a person of ordinary skill in the art to substitute ANP for human calcitonin or CNP as per teachings of Yabuta et al. because the same result should be expected when using ANP in place of CNP or clacitonin. It would be predictable that the method would work with ANP because Yabuta et al. showed that the method was successful with calcitonin and CNP, and stated that the same method would work for ANP.

One would be motivated to use ANP in place of calcitonin or CNP because the steps in the method disclosed by Yabuta et al. would be the same, and the expectation of success would be high because of the great results achieved by Yabuta et al.

Claim 9 is rejected because the preamble states "*a method for reducing formation of a byproduct polypeptide comprising an o-acetylserine residue in place of a serine residue, comprising.*" however the invention only requires culturing transformed host cells in a medium comprising at least one histidine, methionine or glycine in an effective amount to reduce the formation of a byproduct polypeptide. The recitation of o-acetylserine is limited to the preamble of the claims or as the inherent end-point of the claimed method. *In re Hirao*, 535, F.2d 67, 190 USPQ 15 (CCPA 1976), the court states that a preamble is generally not accorded any patentable weight where it merely recites the purpose of a process or the intended use of a structure, and where the body of the claim does not depend on the preamble for completeness, but instead, the process steps or structural limitation are able to stand alone.

In Claims 10-12, the Applicant claims o-acetylserine as a byproduct formed in the method of production of an atrial natriuretic peptide comprising a serine residue.

MPEP section 2105 states that language that suggests or makes optional, but does not require steps to be performed or does not limit a claim to a particular structure does not limit the scope of a claim or claim limitation. For example, a language that may raise a question as to the limiting effect of the language in a claim are statements of intended use or field of use.

In claims 10-12, the byproduct o-acetylserine has no effect on the steps performed in the method, therefore o-acetylserine does not limit the claims.

Therefore, it would have been obvious to one skilled in the art to design a method for the production of a protein comprising culturing E.coli host cells transformed with a plasmid capable of expressing the protein, where the protein produced is the human atrial natriuretic peptide as suggested by Yabuta et al., and where the byproduct formed is in a form of o-acetyl-serine. One would be motivated to produce the atrial natriuretic peptides because of the success of the method in producing a human calcitonin as taught by Yabuta et al.

Conclusion

No Claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Agnes Rooke whose telephone number is 571-272-2055. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber can be reached on 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have any questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197.

AR



KAREN COCHRANE CARLSON, PH.D
PRIMARY EXAMINER